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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,463	04/05/2001	Nobuto Yamamoto	Y1004/20017	2419

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CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.
12TH FLOOR, SEVEN PENN CENTER
1635 MARKET STREET
PHILADELPHIA, PA 19103-2212

EXAMINER
ROMEO, DAVID S

ART UNIT	PAPER NUMBER
1647	3

DATE MAILED: 02/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/826,463	YAMAMOTO, NOBUTO	
	Examiner	Art Unit	
	David S Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *5-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The preliminary amendment has been entered.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 1-3 been renumbered 21-23.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 22, 23, drawn to enzymatic production of a GcMAFc protein or polypeptide, classified in class 435, subclass 68.1.

II. Claim 6, drawn to a method of treating cancer comprising administering a GcMAFc protein or polypeptide, classified in class 514, subclass 12.

III. Claim 9, to the extent that it is drawn to a method of treating a person with HIV comprising administering a GcMAFc protein or polypeptide, classified in class 514, subclass 12.

IV. Claim 9, to the extent that it is drawn to a method of treating a person with EBV comprising administering a GcMAFc protein or polypeptide, classified in class 514, subclass 12.

V. Claim 9, to the extent that it is drawn to a method of treating a person with herpes zoster comprising administering a GcMAFc protein or polypeptide, classified in class 514, subclass 12.

VI. Claims 11, 16, 18, drawn to a GcMAFc protein or polypeptide, classified in class 530, subclass 350.

VII. Claim 13, drawn to a method of promoting bone marrow formation in osteopetrotic patients comprising administering a GcMAFc protein or polypeptide, classified in class 514, subclass 12.

VIII. Claim 7, drawn to a method treating cancer comprising administering a CdMAF protein or polypeptide, classified in class 514, subclass 12.

IX. Claim 10, to the extent that it is drawn to a method of treating a person with HIV comprising administering a CdMAF protein or polypeptide, classified in class 514, subclass 12.

X. Claim 10, to the extent that it is drawn to a method of treating a person with EBV comprising administering a CdMAF protein or polypeptide, classified in class 514, subclass 12.

XI. Claim 10, to the extent that it is drawn to a method of treating a person with herpes zoster comprising administering a CdMAF protein or polypeptide, classified in class 514, subclass 12.

XII. Claims 12, 17, 19, 20, drawn to a CdMAF protein or polypeptide, classified in class 530, subclass 300.

XIII. Claim 5, drawn to a method of treating cancer comprising administering a GcMAF protein or polypeptide, classified in class 514, subclass 12.

XIV. Claim 8, to the extent that it is drawn to a method of treating a person with HIV comprising administering a GcMAF protein or polypeptide, classified in class 514, subclass 12.

XV. Claim 8, to the extent that it is drawn to a method of treating a person with EBV comprising administering a GcMAF protein or polypeptide, classified in class 514, subclass 12.

XVI. Claim 8, to the extent that it is drawn to a method of treating a person with herpes zoster comprising administering a GcMAF protein or polypeptide, classified in class 514, subclass 12.

XVII. Claim 15, drawn to a GcMAF protein or polypeptide, classified in class 530, subclass 350.

XVIII. Claim 21, drawn to modification or preparation of a recombinant DNA vector, classified in class 435, subclass 91.4.

The inventions are distinct, each from the other because of the following reasons:

The following pairwise combinations of methods are independent and distinct, wherein each member of a pair performs different functions, and/or using different starting materials and/or process steps and/or with different outcomes:

II and each of III, IV, V, VII, VIII, IX, X, XI, XIII, XIV, XV, XVII, XVIII; III and each of IV, V, VII, VIII, IX, X, XI, XIII, XIV, XV, XVII, XVIII; IV and each of V, VII, VIII, IX, X, XI, XIII, XIV, XV, XVII, XVIII; V and each of VII, VIII, IX, X, XI, XIII, XIV, XV, XVII, XVIII;

VII and each of VIII, IX, X, XI, XIII, XIV, XV, XVII, XVIII; VIII and each of IX, X, XI, XIII, XIV, XV, XVII, XVIII; IX and each of X, XI, XIII, XIV, XV, XVII, XVIII; X and each of XI, XIII, XIV, XV, XVII, XVIII; XI and each of XIII, XIV, XV, XVII, XVIII; XIII and each of XIV, XV, XVII, XVIII; XIV and each of XV, XVII, XVIII; XV and each of XVII, XVIII; XVII and each of XVIII. Furthermore, the arts of HIV, EBV, and herpes zoster are independent and distinct, requiring separate searches in areas of the literature that are not co-extensive.

Inventions I and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make XII; the product as claimed can be made by another and materially different process using XVII.

Inventions VI and each of II-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with XII or XVII. The product as claimed can be used as an antigen for the production of antibodies thereto or in vitro in cell culture.

The following pairwise combinations of products and methods are independent and distinct, wherein the respective products are neither produced by, nor required for the use of the

respective methods: VI and each of VII-XI, XIII-XVI, XVIII; XII and each of I-V, XIII-XVI, XVIII; XVII and each of I-V, VII-XI, XVIII.

Inventions XII and each of VII-XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with VI or XVII. The product as claimed can be used as an antigen for the production of antibodies thereto or in vitro in cell culture.

Inventions XVII and each of XIII-XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with VI or XII. The product as claimed can be used as an antigen for the production of antibodies thereto or in vitro in cell culture.

The following pairwise combinations of products are independent and distinct, wherein neither member of a pair is required for the production or use of the other, wherein each is structurally distinct and requires separate searches that are not co-extensive, and wherein each of the pair can be manufactured independently of the other and used for independent and distinct purposes: VI and each of XII, XVII; XII and XVII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the searches required are not coextensive, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: SEQ ID NO: 2 and SEQ ID NO: 3.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, group XII is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306
AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
JANUARY 31, 2003